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Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 3642-1 (1990): Surgical instruments, Part 1: Non-cutting articulated instruments [MHD 1: Surgical Instruments]

“ज्ञान से एक नये भारत का निर्माण”

Satyanaaranay Gangaram Pitroda

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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

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“Knowledge is such a treasure which cannot be stolen”



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(दूसरा पुनरीक्षण)

Indian Standard

SURGICAL INSTRUMENTS — SPECIFICATION

PART 1 NON-CUTTING, ARTICULATED INSTRUMENTS

(Second Revision)

UDC 615.471 : 620.1

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CONTENTS

	PAGE
1 SCOPE	1
2 REFERENCES	1
Section 1 General Requirements	
3 MATERIALS	1
4 TYPES, SHAPES, SIZES AND DIMENSIONS	1
5 HEAT TREATMENT AND HARDNESS	1
6 DESIGN AND WORKMANSHIP	1
7 SURFACE FINISH	2
8 CORROSION RESISTANCE	2
9 ELASTICITY	2
10 PERFORMANCE OF NEEDLE HOLDERS	2
11 TESTS	2
TABLE 1 TEST WIRE FOR ELASTICITY TEST FOR CLAMPING INSTRUMENTS	3
Section 2 Serrations	
12 PROFILE OF SERRATIONS	4
FIG. 1 SERRATIONS FOR SURGICAL INSTRUMENTS	4
FIG. 2 EXAMPLES OF JAW SERRATIONS	5
TABLE 2 PITCH AND PREFERRED DEPTH OF SERRATIONS	5
Section 3 Joints	
13 JOINTS	6
FIG. 3 JOINTS FOR DISSECTING FORCEPS	6
FIG. 4 EXAMPLES OF SCREW JOINTS	7
FIG. 5 EXAMPLE OF BOX JOINT	8
Section 4 Ratchet Teeth	
14 REQUIREMENTS FOR RATCHET TEETH	7
FIG. 6 RATCHET TEETH FOR SURGICAL INSTRUMENTS	9
Section 5 Teeth and Prongs	
15 REQUIREMENTS FOR TEETH (PRONGS)	8
FIG. 7 TEETH FOR SURGICAL INSTRUMENTS	9
Section 6 Finger Loops	
16 REQUIREMENTS FOR FINGER LOOPS	9
FIG. 8 FINGER LOOPS FOR SURGICAL INSTRUMENTS	9
TABLE 3 SIZES AND DIMENSIONS OF FINGER LOOPS	9
Section 7 Marking, Packing and Sampling	
17 MARKING AND PACKING	10
18 SAMPLING	10
ANNEX A SAMPLING PLAN AND CRITERIA FOR CONFORMITY OF SURGICAL INSTRUMENTS	10

(Continued on third cover)

Indian Standard

SURGICAL INSTRUMENTS — SPECIFICATION

PART 1 NON-CUTTING, ARTICULATED INSTRUMENTS

(Second Revision)

1 SCOPE

1.1 This standard specifies the requirements for a general range of non-cutting, articulated instruments used in surgery.

1.1.1 The general range of instruments shall cover artery forceps, dissecting forceps, tissue forceps, needle holders, clamps and other instruments of similar design. It shall, however, not include special purpose, non-cutting articulated instruments such as midwifery forceps, nasal forceps, peritonsillar forceps, eye needle holders barraquer's pattern, etc.

2 REFERENCES

The Indian Standards listed below are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 (second revision)
4218	ISO metric screw threads
4905 : 1968	Methods for random sampling
6528 : 1972	Stainless steel wire
6603 : 1972	Stainless steel bars and flats
6911 : 1972	Stainless steel plate, sheet and strip
7531 : 1991	Method of testing for corrosion resistance of stainless steel surgical instruments (first revision)

SECTION 1 GENERAL REQUIREMENTS

3 MATERIALS

The component parts including rivets and screws shall be made of stainless steel conforming to designation 20Cr13 or 30Cr13 of IS 6603 : 1972 or IS 6911 : 1972 as the case may be.

4 TYPES, SHAPES, SIZES AND DIMENSIONS

4.1 Types, shapes, sizes and dimensions shall be according to the relevant Indian Standards. In the absence of a standard, these shall be as per user's requirements, which shall clearly specify dimensions on the same lines as given in an Indian Standard for an identical instrument.

4.2 Tolerances

Tolerances on dimensions, where not specified in the relevant Indian standards, shall be as follows:

a) *On Linear Dimensions*

- ± 0.05 mm on dimensions up to 2.0 mm
- ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm
- ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm
- ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm
- ± 1.0 mm on dimensions above 50.0 mm and up to 100.0 mm
- ± 2.0 mm on dimensions above 100.0 mm

b) *On Angular Dimensions* ± 2°

5 HEAT TREATMENT AND HARDNESS

5.1 General

The component parts of the instrument excluding rivets, screws and inserts shall be heat treated using hardening and tempering procedures so as to produce the specified hardness throughout the instruments.

5.2 Hardness

The Vickers hardness of the finished instrument excluding rivets, screws and inserts shall be within the range specified below, when tested in accordance with IS 1501 (Part 1) : 1984:

Hardness for 20Cr13 stainless steel instruments : 390 to 460 HV

Hardness for 30Cr13 stainless steel instruments : 410 to 485 HV

5.3 The mating surfaces on the same instrument such as opposite jaws and shanks shall not vary in hardness by more than 40 HV.

6 DESIGN AND WORKMANSHIP

6.1 General

6.1.1 There shall be no sharp edges other than those specified for the functioning of the instruments.

6.1.2 The arms of the instrument, wherever applicable, shall be symmetrical and balanced. The jaws shall close and open smoothly with even movement and without jerk.

6.2 Serrations

The requirements of serrations, where provided, shall be as specified in Section 2.

6.3 Joints

The requirements of joints shall be as specified in Section 3.

6.4 Ratchet Teeth

The requirements for ratchet teeth, where provided, as for box jointed and screw jointed instruments, shall be as specified in Section 4.

6.5 Teeth

The requirements for teeth used for dissecting and similar purposes shall be as specified in Section 5.

6.6 Finger Loops

The dimensional requirements of common type of finger loops, where provided, shall be as specified in Section 6.

7 SURFACE FINISH

7.1 All surfaces shall be free from pores, crevices and grinding marks. The instrument shall be free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

7.2 The surface finish shall be one of, or a combination of, the following:

- a) Mirror finish; and
- b) Reflection-reducing, for example satin finish, matt black finish.

NOTES

1 The satin finish should be achieved by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks to achieve a mirror finish. This should be effected by an appropriate procedure, such as polishing, brushing, electropolishing and mirror buffing.

7.3 Passivation and Final Treatment

The instruments shall, unless the metallurgical characteristics of the instrument renders it inappropriate (for example, the presence of brazed or soldered joints), be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian pharmacopoeia.

8 CORROSION RESISTANCE

The instruments, when tested for corrosion resistance in accordance with IS 7531 : 1990, shall pass the test.

9 ELASTICITY

The instruments, shall be tested for elasticity in accordance with 11.2 and 11.3 depending on the type of instrument. After the test, no distortion, cracks or any permanent set shall be visible.

10 PERFORMANCE OF NEEDLE HOLDERS

10.1 The needle holders shall be subjected to performance test in accordance with 11.4. During the test, the fibre shall not slip out, irrespective of whether direction of the load is longitudinal or transverse.

11 TESTS

11.1 Load Closure Test

11.1.1 This test shall be applicable to dissecting forceps only.

11.1.2 The arms shall be capable of full closure, when a load as prescribed below is applied at the beginning of the first finger groove or the roughened surface:

<i>Length of Forceps mm</i>	<i>Closure Load ± 50 g</i>
130	200
145	250
160	300
180	350
200	400
250	450

On closing the arms, with the closure load applied, the tips of forceps shall not gape.

11.2 Elasticity Test for Clamping Instruments (Including Needle Holders)

11.2.1 General

This test shall be applicable to clamping instruments having ratchet and finger loops. This test shall be performed in two parts; first part shall be performed for checking the elasticity of working part and joint (11.2.2) and the second part for testing the elasticity of shanks (11.2.3).

11.2.2 Place a test wire in accordance with Table 1, between the working portions at the tip of the instrument. Fully close the instrument (to the last ratchet position). Leave the instrument under this strain for 3 h at room temperature. Examine the instrument. No distortion, cracks, or any other permanent deformation shall be allowed.

Table 1 Test Wire for Elasticity Test for Clamping Instruments

All dimensions in millimetres.

Test Wire	Diameter of Test Wire	Nominal Length (Overall Length) of the Instrument
Wire of stainless steel as per IS 6528 : 1972	0·8 1	Up to 160 } Over 160 }
Grade—04Cr18Ni10	2	Up to 150
Condition—‘S’	3	Over 150 to 200
	4	Over 200

⁽¹⁾For needle holders only.

11.2.3 Each arm of the instrument shall be fixed in a vice so that the entire arm protrudes from the upper surface of the vice jaws.

Nominal Length of the Instrument (Overall Length)	Deflection mm
mm	mm
Up to 150	8
From 150 to 200	10
From 200 to 250	12

By the application of gradual force at the upper pole of the finger loop, the shank of the instrument shall be deflected in a plane at right angles to that of the finger loop by the amount shown above as measured at the upper extremity of the clamped arm (that is, at the upper pole of the finger loop). On release of the force, no permanent set shall be observed. The test shall be repeated on the same arm with the finger loop fixed at its equator in the vice and the shank projecting above the vice. The deflecting force shall be applied to the shank at a point 20 mm below the joint (screw/box joint) of the instrument and shall act in a plane at right angles to that of the finger loop. The shank shall be deflected by the above amount shown above as measured at the level of the point where the force is applied. On release of the force, the instrument shall not take a permanent set. The complete test shall be repeated on the opposite arm.

11.3 Elasticity (Flexibility) Test for Dissecting Forceps

11.3.1 The arms of the forceps after maximal closure by manual compression shall not take a permanent set and the serrations/teeth shall continue to engage and disengage accurately and properly.

11.3.2 The joint end of the forceps shall be fixed in a vice so that the riveted, welded or parallel portion of the folded joint is gripped firmly. In case of forceps with folded joint, the joint shall be tightly interleaved with an aluminium strip before fixing the forceps in the vice, so that the deformation of the joint is avoided. By the application of force at the tip of the arm, one arm of the forceps shall be deflected in a plane at right angles to the plane of the arm, by the distance shown below as measured at the tip of the forceps:

Forceps of Length mm	Deflection mm
From 130 to 150	25
From 150 to 200	30
More than 200	35

On release of the force, no permanent set shall be observed.

The test shall be repeated on the opposite arm.

11.4 Performance Test for Needle Holders

Place a plastic fibre (for example a suture filament) of 0·2 mm maximum diameter between the jaws of the instrument at a point within the 1/3 of the length nearest the tip. Now, fully close the instrument and apply a tensile force of 20 N to the fibre. Record whether the fibre is pulled out from the jaws.

11.5 Tests for Engagement of Serrations

11.5.1 Engagement of Tips

Tips of the instrument shall be closed on the edge of a piece of thin paper in such a way that only the first pair of serration engages. The instrument shall be pulled away from the edge taking the bite of the paper in its tips such that the instrument does not get twisted. A small fragment of paper having the shape of the nose of instrument shall be cleanly cut out.

11.5.2 Engagement of Jaws

11.5.2.1 This test applies to forceps with toothed ends.

The forceps shall be made to grip a piece of chamois leather 1 mm thick and the forceps pulled away holding firmly the chamois leather. The forceps shall not slip.

11.5.2.2 This test applies to clamping instruments having ratchet and finger loops.

On closing the jaws, the serrations shall engage accurately and the engagement shall commence at the extreme tip and progress along the entire length of serrations. If the instrument is with two ratchets (2 in 1 and 2 in 2), the tip of the jaw shall meet at the first contact of the ratchet and shall engage 2/3rd of the serrated length, on the engagement of the first ratchet. The entire length of the serration shall fully engage on the closure of second tooth of the ratchet. If the instrument is with 3 or more ratchets (3 in 1, 3 in 2, 3 in 3, and 4 in 1, 4 in 3, etc) the tip of the jaw shall meet at the first contact of the first ratchet and shall fully engage the entire length of the serrations on the closure of the second tooth of the ratchet. The closure of the third and/or fourth tooth of the ratchet shall be used to apply extra pressure at the jaws.

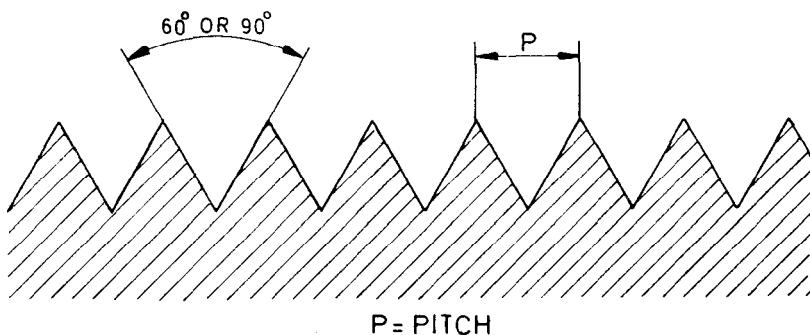
NOTE — Entire length means 90 percent length of the serrated portion of the jaws from the tip. The last 10% of the length is generally left unmatched to facilitate tool relief and also escape route for the excessive pressure.

SECTION 2 SERRATIONS

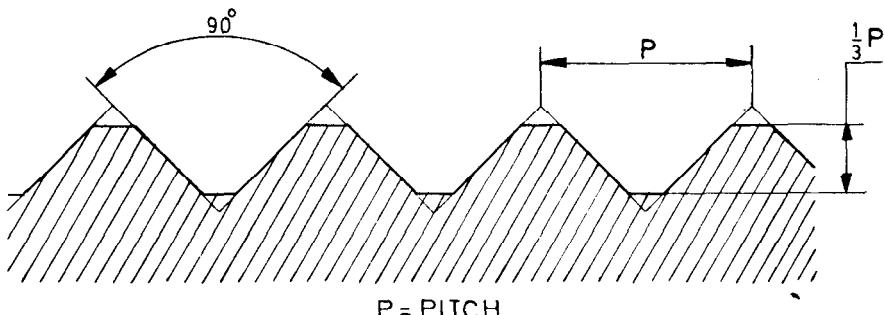
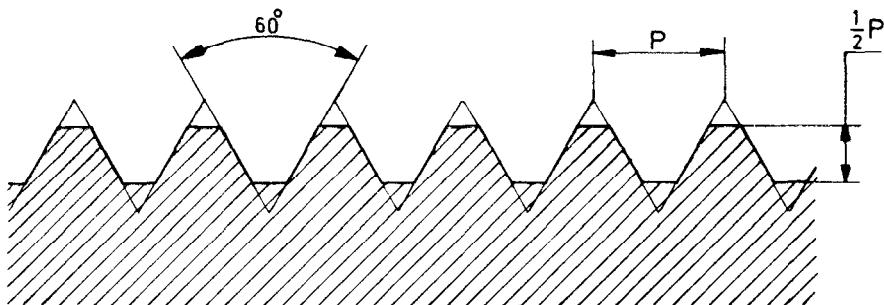
12 PROFILE OF SERRATIONS

12.1 Profile of serrations shall be in accordance with Fig. 1A. The angle of the profile shall be 60° or 90°.

12.2 Serrations of the jaws shall have the crest truncated. Pitches of serrations and preferred depths of truncation shall be as shown in Table 2 and Fig. 1B with the crests and troughs being flat across the inner face of the jaw. Depth of the serrations shall be uniform throughout and the serrations shall be true and square with the jaw of the instrument. The serrations shall so match as to register properly without overriding, sticking or locking. When the pressure on the jaws is released, serrations should part freely without catching.



1A Profile of Serrations for Surgical Instruments



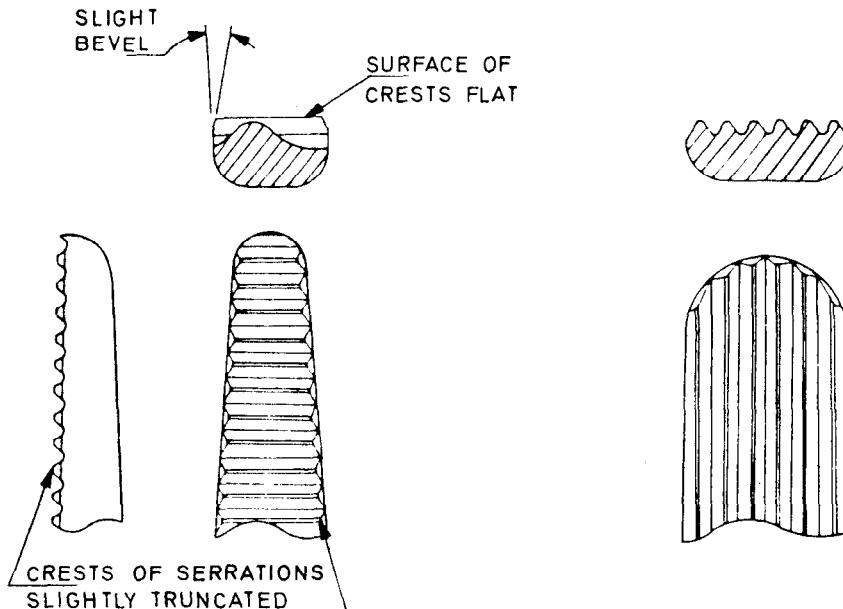
1B Truncation of Serrations

FIG. 1 SERRATIONS FOR SURGICAL INSTRUMENTS

Table 2 Pitch and Preferred Pitch of Serrations
(Clause 12.2 and Fig. 1B)

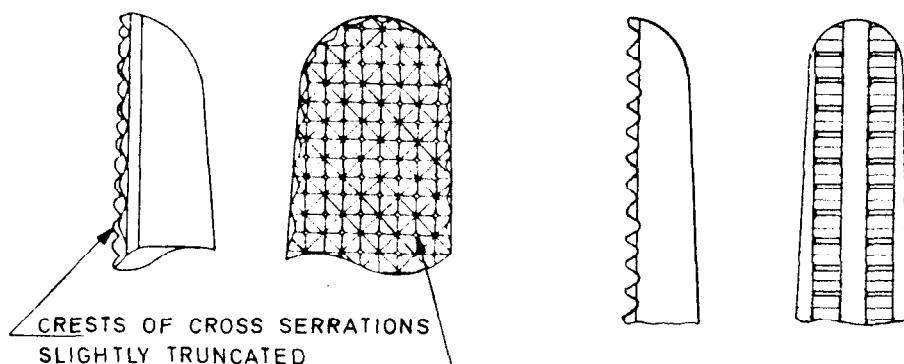
All dimensions in millimetres.

Pitch	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.25	1.5	1.75	2.0	2.5	3.0
Preferred $1/2P$ =	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.63	0.75	0.88	1.0	1.25	1.5
Depth $1/3P$ =	0.10	0.13	0.17	0.20	0.23	0.27	0.30	0.33	0.42	0.50	0.58	0.67	0.83	1.0



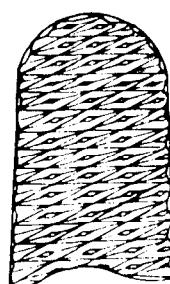
2A Transverse Serrations

2B Longitudinal Serrations



2C Metal Insert Jaw Needle Holder

2D Atraugrip Jaw Serrations



2E Solid Jaw Needle Holder

FIG. 2 EXAMPLES OF JAW SERRATIONS

12.3 Serrations shall be either perpendicular or parallel to the axis of the instrument as required (see Fig. 2). If the oblique serrations are required, preferred angle shall be 60° or 45° to the axis of the instrument. When the serrations are engaged, they shall match crests to troughs and pass the tests as given in 11.5.

12.4 If the serrations are required to form a diamond pattern, the cross serrations shall subtend equal and opposite angles with the axis of the instrument.

12.5 Atraugrip Serrations

Atraugrip serrations shall have two rows of finely serrated teeth on one jaw and one row on the other jaw, each set in a separate parallel plane, providing a non-cutting, non-traumatic triangular grip in order to assure complete occlusion of blood vessels without danger of crushing or perforation.

12.6 Uniformity of Serrations

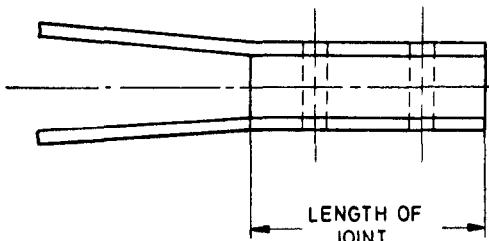
Serrations of the jaws shall be tested for uniformity, freedom from rough edges and burrs and also for correct registration of jaws, on a dry and long fibred lens cleaning tissue paper. On releasing the jaws, the tissue paper shall have a clear imprint of all serrations and shall not show any cuts or tears.

SECTION 3 JOINTS

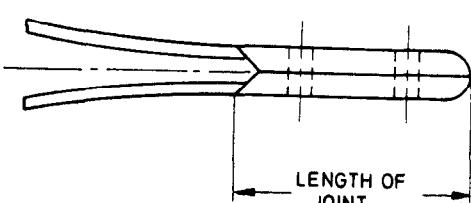
13 JOINTS

13.1 Joints for Instrument of the Dissecting Forceps Type

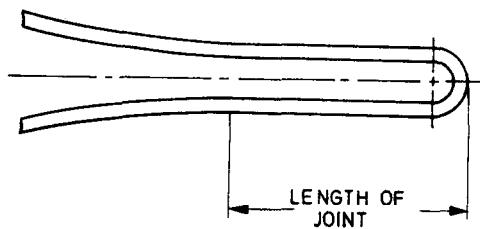
Joints for instruments shall either be block joint shown in Fig. 3A or semi-block joint shown in Fig. 3B or fold joint shown in Fig. 3C. Block joint shall be in three parts and the semi-block joint shall be in two parts. In both types of joints, at least two rivets shall be used with their heads finished flush with surface of the joint. The block joint and the semi-block joint may be spot welded in place of riveting.



3A Block Joint



3B Semi-Block Joint



3C Fold Joint

FIG. 3 JOINTS FOR DISSECTING FORCEPS

13.1.1 The details of the joint are shown in Fig. 3A to 3C and shall be in accordance with the individual specifications. In the case of fold joint, the length of the parallel portion shall be the length of joint.

13.1.2 There shall be no gap or crevice between the component part of the block or semi-block joint. The joint shall be true and square so as to permit balanced and matching movement of the arms of the instrument.

When examined visually, no movement shall be discernible in the joint. All types of joints and turn over ends shall be so designed as to facilitate cleaning and sterilization of the instrument. There shall be no crevices between component parts of the joints. The joint faces shall be clean and free from scale before assembly.

13.2 Joints for Clamping Instruments

13.2.1 Screw Joints

13.2.1.1 Examples of screw joints are shown in Fig. 4.

13.2.1.2 The screw joint shall be symmetrically made and basically of rectangular section in order to achieve maximum strength in the joint. In some cases rounding off the corners may be permitted. Working clearances shall be kept to a minimum in order to avoid unnecessary gaps. If possible without detriment to the strength of the joint, the ends of the screw shall be ground flush with the surface of the instrument. Screws shall be immovable but capable of being unscrewed for repairs.

13.2.1.3 The joint shall function smoothly without undue shake or play and be neither too loose nor too tight and it shall be possible to open and close the instrument easily with two fingers.

13.2.1.4 The screws shall have metric threads in accordance with IS 4218.

13.2.2 Box Joints

13.2.2.1 An example of the box joint is shown in Fig. 5. The box joint shall be symmetrically made and be basically of rectangular section in order to achieve maximum strength in the joint. Centre member shall be 40 percent and each side member shall be 30 percent of the total thickness of the box joint. The rivet shall be finished flush with the surface of the joint.

13.2.2.2 The joint shall move smoothly and shall be neither too loose nor too tight and it should be possible to open and close the instrument easily with two fingers.

13.2.2.3 Rivets shall be rendered immovable. The rotation of the rivet may be prevented, for example, by the use of a suitably shaped counter-sink in the outer member of the joint. An example of the box joint is shown in Fig. 5. The box joint should be symmetrically made and be basically of rectangular section in order to achieve maximum strength in the joint.

SECTION 4 RATCHET TEETH

14 REQUIREMENTS FOR RATCHET TEETH

14.1 Unless otherwise specified in individual standards, the ratchet teeth shall conform to dimensions given in Fig. 6A or 6B. The teeth shall be well cut uniform, regular and even in spacing and depth. Preferred pitches of teeth shall be 2, 3 and 4 mm. Teeth on both shanks shall have either of the following combinations:

1 in 2 2 in 2
1 in 3 3 in 3

For special purpose, the combinations may be as specified by the purchaser or as per individual specifications. Ratchet shall be capable of easy, full and secured engagement without any tendency to slip or possibility of over-engagement. It shall be capable of disengaging without any undue stiffness or jumping. Ratchets on both shanks of the instrument shall be well-aligned. All sharp edges and corners shall be removed and there shall be no tendency to collect dirt or filthy matter. The ratchet shall be finished smooth without any pits or machine marks or other surface defects.

14.2 Load Test

With the ratchet of the instrument disengaged, one (lower) finger loop shall be clamped in a vice such that the instrument is held in a horizontal position like a cantilever. A load shall be applied at the other (upper) finger loop by means of a pan or a spring balance and shall be gradually increased till the first ratchet just engages. The maximum load required to close the instrument at different steps of the ratchet shall be as given in the relevant standard of the instrument or as required by the purchaser.

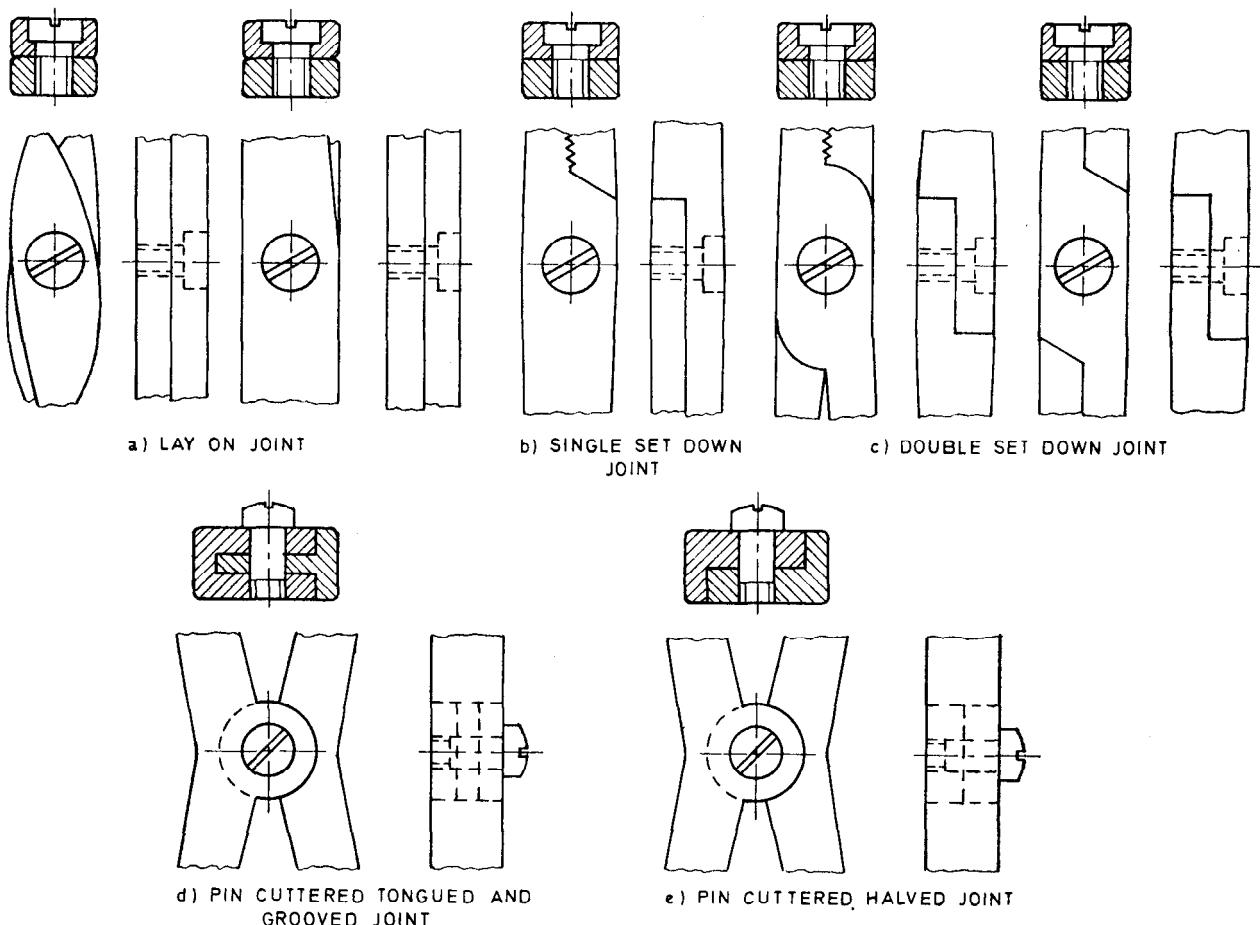


FIG. 4 EXAMPLES OF SCREW JOINTS

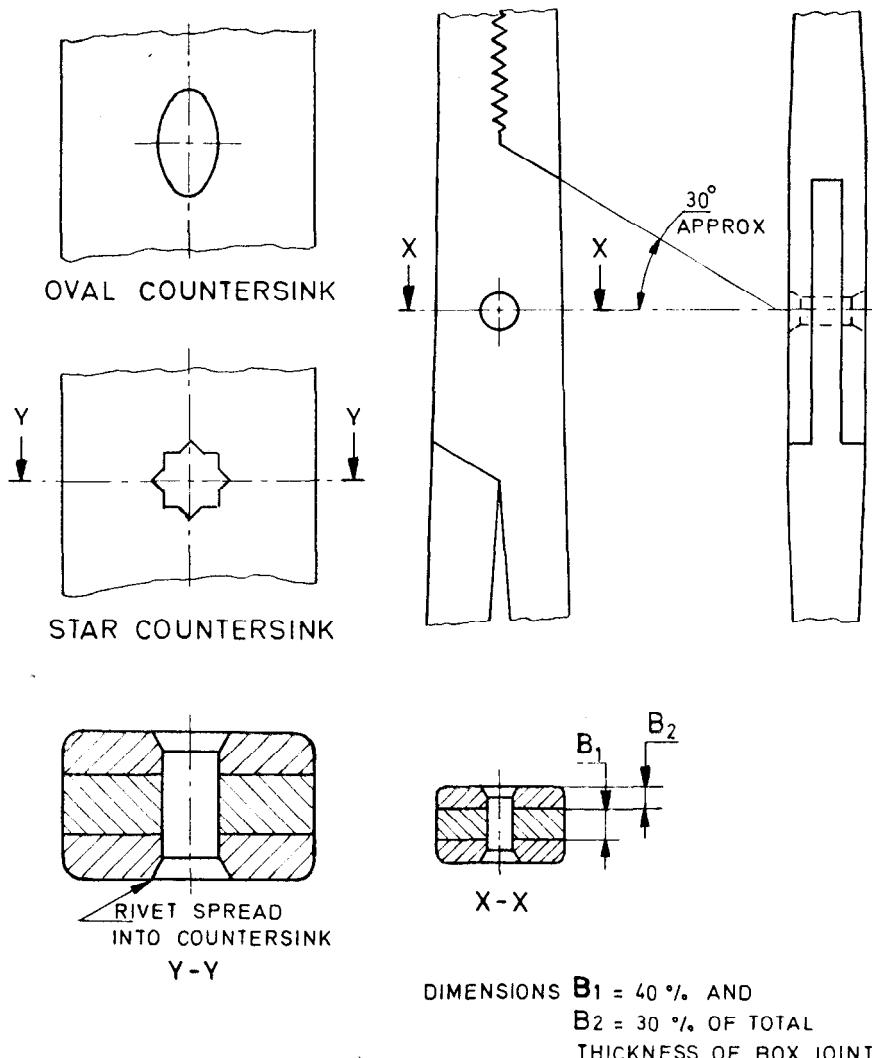
SECTION 5 TEETH AND PRONGS

15 REQUIREMENTS FOR TEETH (PRONGS)

15.1 Profile of teeth (prongs) shall be as given in Fig. 7. Teeth may be in combination of 1 in 2, 2 in 3 or as specified in individual specifications, for example, 3 in 4, 4 in 5, etc. Teeth shall either be pointed (*see* Fig. 7A) or flat ended (*see* Fig. 7B). The dimensions of flat end shall be as specified to suit different purposes but shall be between 0.2 and 0.4 mm. Teeth shall match perfectly and shall slide into engagement truly and smoothly

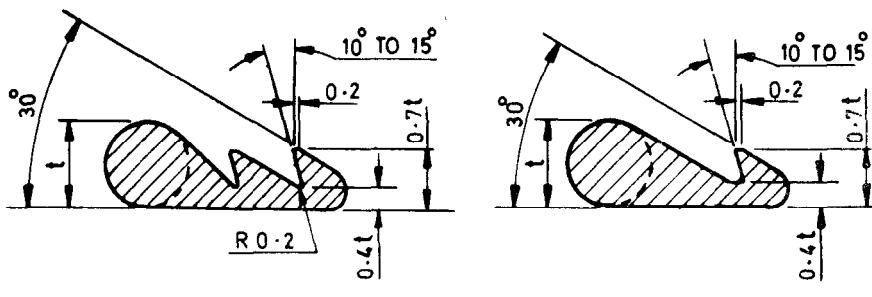
without undue effort. The teeth and prongs shall part freely without catching when the pressure on the jaws is released. They shall be uniformly spaced and symmetrical with respect to central line of each arm of the instrument and shall be true to the surface of the arm. Teeth shall be finished smooth without any pits or machine marks or other surface defects.

15.2 In case of dissecting forceps, the guide pin, if provided, shall be tapered to facilitate entry into the locating hole and shall not protrude from the hole when the jaws are closed.

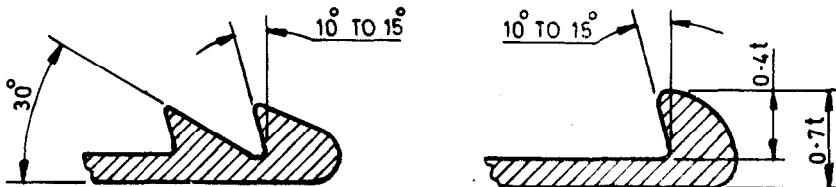


The oval and star countersink are examples of the methods used to prevent rotation of the rivet.

FIG. 5 EXAMPLE OF BOX JOINT



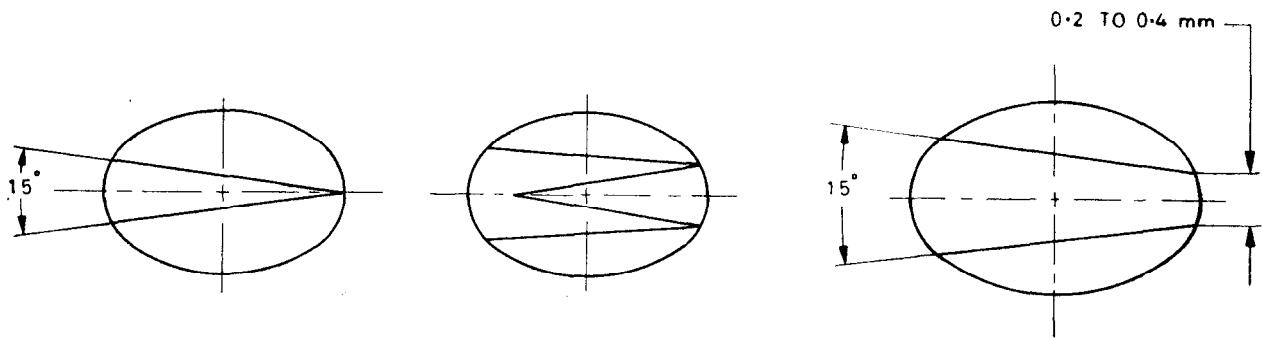
6A Ratchet Teeth



6B Ratchet Teeth, Alternate

All dimensions in millimetres.

FIG. 6 RATCHET TEETH FOR SURGICAL INSTRUMENTS



1 IN 2 TEETH

2 IN 3 TEETH

7B

FIG. 7 TEETH FOR SURGICAL INSTRUMENTS

SECTION 6 FINGER LOOPS**16 REQUIREMENTS FOR FINGER LOOPS**

16.1 Finger loop for surgical instruments shall be of the shape shown in Fig. 8 read with Table 3. It shall be of any of the four sizes specified according to the size of the instrument.

shall be rounded. Each finger loop shall be in the same plane as the arm of the instrument.

Table 3 Sizes and Dimensions of Finger Loops

Dimension	Size			
	No. 1 mm	No. 2 mm	No. 3 mm	No. 4 mm
A	22	26	28	30
B	18	20	22	22
C	2	2	2.5	3
D	3	3	3.5	4

16.2 Loops, unless specified otherwise in individual specification, shall be of the same size on both arms of the instruments and they shall provide a comfortable finger grip. All sharp edges

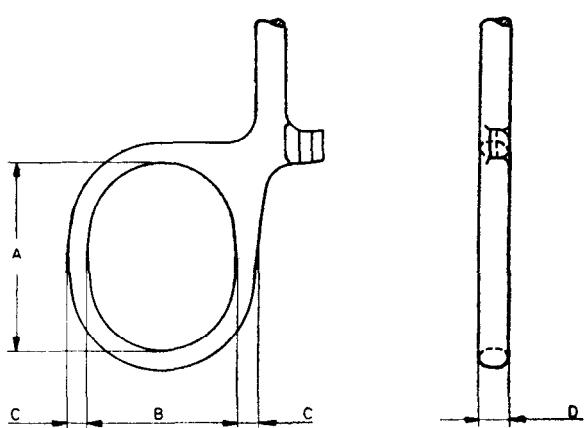


FIG. 8 FINGER LOOPS FOR SURGICAL INSTRUMENTS

SECTION 7 MARKING, PACKING AND SAMPLING**17 MARKING AND PACKING****17.1 Marking**

Non-cutting articulated surgical instruments shall be legibly and indelibly marked with the identification of the source of manufacture; designation of the instrument and letters 'SS' to indicate that the instruments are made of stainless steel.

17.2 Packing

The instruments may either be put in polyethylene bags or wrapped in wax paper.

18 SAMPLING

18.1 The scale of sampling and criteria for conformity of the instrument to requirements of the specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A*(Clause 18.1)***SAMPLING PLAN AND CRITERIA FOR CONFORMITY OF SURGICAL INSTRUMENTS****A-1 LOT**

A-1.1 In any consignment, all the instruments of the same type and pattern produced from the same material under similar conditions and having the same surface finish shall constitute a lot.

A-2 NUMBER OF INSTRUMENTS

A-2.1 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 4.

A-2.2 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS 4905 : 1968 may be followed.

Table 4 Scale of Sampling
(Clauses A-2.1, A-3.2 and A-3.3)

Lot Size (1)	Sample Size (2)	Sub-sample Size (3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 For ascertaining the conformity of the material to the requirements of the specification, samples shall be tested from each lot separately.

A-3.2 All the instruments, selected according to col 1 and 2 of Table 4 shall be examined for shape and dimensions, workmanship and surface condition (visual), engagement of serrations, ratchet teeth and teeth of jaws. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as having satisfied these requirements, if there is no defective in the sample.

A-3.3 The lot having been found satisfactory according to A-3.2 shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 4 shall be taken. These instruments in the sub-sample may be selected from those already examined according to A-3.2. Each instrument in the sub-sample shall be subjected to hardness, performance (where applicable), load closure, elasticity (flexibility) and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification, if none of the instruments in the sub-sample fails in any of these tests.

(Continued from second cover)

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards on 23 November 1990, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1966 and was subsequently revised in 1978. Second revision of this standard has been taken up to effect certain modifications based on the experience gained due to implementation of this standard and to align it with the latest practices being followed in the field at the national, as well as international level.

This standard covers general requirements, common design features and test methods for non-cutting articulating type surgical instruments, which are applicable to a large variety of surgical instruments such as artery forceps, tissue forceps, dissecting forceps, needle holders and clamps.

Thus this standard is expected to serve as a horizontal standard for all such instruments and would form a necessary adjunct for their respective standards. As a result of this, it is intended to revise all the existing standards on non-cutting articulated type instruments, so as to cover only the dimensional and other specific requirements, which cannot be generalized. This would help in speedier implementation of Indian Standards in the field of surgical instruments.

This standard is being published in two parts. The other part is:

Part 2 'Cutting type, articulated instruments'

In preparing this standard, assistance has been derived from the following publications:

DIN 58299 : 1964 Serrations for surgical instruments, profile, angle and pitch. Deutsches Institut für Normung.

ISO 7151 : 1988 Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods. International Organization for Standardization.

BS 5194 (Part 2) : 1985 Surgical instruments : Part 2 Specification for instruments with pivot joints (excluding cutting instruments). British Standards Institution.

BS 5194 (Part 3) : 1985 Surgical instruments : Part 3 Specification for dissecting forceps. British Standards Institution.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Doc : No. MHD 1 (2198)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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